

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FTC and THE PEOPLE OF THE) Case No.
STATE OF NEW YORK) 17-cv-124 (LLS)
)
Plaintiff)
)
vs.)
)
QUINCY BIOSCIENCE HOLDING)
COMPANY, INC., QUINCY)
BIOSCIENCE, LLC, PREVAGEN)
INC., et al.,)
Defendants)

Remote Videotaped Deposition of
Janet Wittes, Ph.D.
October 7, 2021
10:13 a.m.

Reported by: Bonnie L. Russo
Job No. 200430

1 Remote Videotaped Deposition of Janet Wittes,
2 Ph.D. held through:

21 Pursuant to Notice, when were present on behalf
22 of the respective parties:

1 APPEARANCES:

2 On behalf of the Plaintiff Federal Trade
Commission:

3 ANNETTE SOBERATS, ESQ.
4 FEDERAL TRADE COMMISSION
1 Bowling Green
5 New York, New York 10004

6
7 On behalf of the Plaintiff State of New York:

8 KATE MATUSCHAK, ESQ.
Assistant Attorney General
9 120 Broadway
New York, New York 10271

10
11 On behalf of the Defendant Quincy Bioscience
12 Holding Company, Inc., Quincy Bioscience LLC,
Prevagen, Inc., Quincy Bioscience
13 Manufacturing, LLC:

14 GLENN GRAHAM, ESQ.
CAITLIN HICKEY, ESQ.
15 GEOFFREY CASTELLO, ESQ.
JACLYN METZINGER, ESQ.
16 KELLEY DRYE & WARREN
One Jefferson Road
17 Parsippany, New Jersey 07054

1 APPEARANCES (CONTINUED):

2
3 On behalf of Defendant Mark Underwood:

4 MARK De LEEUW, ESQ.
TAMAR WISE, ESQ.
5 COZEN O'CONNOR
3 World Trade Center
6 175 Greenwich Street
New York, New York 10007
7

8
9
10
11
12 Also Present:
Andrew Wone, FTC
13 Will Ducklow, FTC
David Ovadia, FTC
14 Jane Azia, Director of Consumer Protection
Michael Pineiro, Videographer
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1 JANET WITTES, PH.D.

2 reports you submitted in this action, do you
3 have any other experience with Prevagen or
4 apoaequorin?

5 A. No, I don't.

6 Q. In Paragraph 16 of your report, Dr.
7 Wittes, you state that you discussed some of
8 the elements of designing and analyzing an RCT
9 that are relevant to your analysis of the
10 Madison Memory Study; is that right?

11 A. Yes, that's what I wrote.

12 Q. In your discussion of the elements
13 of designing and analyzing an RCT, what
14 standard are you applying to your analysis as
15 it relates to the Madison Memory Study?

16 A. I am -- the standard I am applying
17 are -- are -- are standard methods of designing
18 and analyzing randomized clinical trials, basic
19 methods in, you know, elementary statistical
20 and clinical trial literature.

21 Q. Are those standards that you are
22 applying to the Madison Memory Study, are they
23 applicable to RCT drug trials?

24 A. Yes, they are applicable to RCT drug
25 trials and to RCTs whatever the intervention

1 JANET WITTES, PH.D.

2 is.

3 Q. What do you mean by "whatever the
4 intervention is"?

5 A. Drug trials, device trials,
6 supplement trials, behavioral trials. It
7 doesn't matter what the intervention is. The
8 principles are the same.

9 Q. When you say "supplement," are you
10 referring to dietary supplement?

11 A. Dietary supplements, food, yes.

12 Q. So in your opinion, is the drug
13 trial standard the same as the dietary
14 supplement trial standard?

15 MS. SOBERATS: Objection.

16 THE WITNESS: From -- from a
17 scientific --

18 MS. SOBERATS: Just a -- just a
19 moment --

20 THE WITNESS: Sorry.

21 MS. SOBERATS: -- let me just place
22 the objection on the record.

23 Objection. That is outside the
24 scope of Dr. Wittes's report and expertise.

25 BY MR. GRAHAM:

1 JANET WITTES, PH.D.

2 Q. You can answer, Dr. Wittes.

3 MS. SOBERATS: You can answer.

4 THE WITNESS: Okay. I can answer?

5 MS. SOBERATS: Yes.

6 THE WITNESS: Okay. I am referring
7 to the way in which scientific -- one -- one
8 interprets, designs, and interprets data from a
9 scientific point of view, and that has -- I
10 actually forgot the language in your -- your
11 question. Can you repeat the question.

12 BY MR. GRAHAM:

13 Q. Sure. So is the standard -- is the
14 drug trial standard for an RCT the same as the
15 dietary supplement standard for an RCT?

16 MS. SOBERATS: Objection. Falls
17 outside the scope of the expert's report and
18 expertise.

19 THE WITNESS: So when I am talking
20 about the standard, I am talking about the --
21 the scientific standard of -- of trials, and
22 those are the same for -- for supplements and
23 for -- for dietary supplements and for drugs.

24 BY MR. GRAHAM:

25 Q. Do you agree with your counsel's

1 JANET WITTES, PH.D.

2 objection that the standard for a dietary
3 supplement clinical trial falls outside your
4 expertise?

5 A. The -- I am having trouble with your
6 word "standard." If you're talking about -- I
7 am talking about the standard -- if I look up
8 in a textbook about how to do a randomized
9 clinical trial, that is in my expertise. If
10 you are talking more generally about standard
11 that has something other than that, that is
12 outside my expertise.

13 Q. So in that textbook example, would
14 there be example of how to do a RCT for a
15 dietary supplement?

16 A. The textbook example wouldn't
17 necessarily talk about what the intervention
18 was. It would just talk about study
19 intervention. It wouldn't make a -- it
20 wouldn't distinguish between drug and dietary
21 supplement.

22 Q. So sitting here today, do you know
23 if there is a standard for RCTs for dietary
24 supplements?

25 MS. SOBERATS: Objection to the form

1 JANET WITTES, PH.D.

2 of that question.

3 THE WITNESS: I don't know what you
4 mean by standard, so I can't answer the
5 question.

6 BY MR. GRAHAM:

7 Q. Is there somewhere that a dietary
8 supplement manufacturer can look to for
9 guidance on how to perform an RCT for its
10 dietary supplement?

11 MS. SOBERATS: Objection. Falls
12 outside the scope of the expert's report and
13 expertise.

14 THE WITNESS: Yeah. I -- I don't
15 know what dietary supplement manufacturers look
16 at when they are designing their studies.

17 BY MR. GRAHAM:

18 Q. So just to clarify, in your opinion
19 is there a different standard for RCTs for
20 drugs and dietary supplements?

21 MS. SOBERATS: Objection to the form
22 of the question.

23 THE WITNESS: Again, I am having a
24 very hard time understanding what you mean by
25 the word standard. So from my point of view

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2 when I think about the standard for the
3 scientific interpretation and design of
4 studies, it's the same. That's the same
5 whether it's a drug or a -- or a biologic or a
6 vaccine or a supplement or a device or
7 behavioral modification. Those are the same.
8 If you are using the word standard in some
9 other sense, that is outside my expertise.

10 BY MR. GRAHAM:

11 Q. Why do you believe they are the
12 same?

13 A. Why do I believe they are the same?
14 Because it's the same -- this is -- this is
15 seventh grade science. You make a hypothesis;
16 you -- you describe what you are supposed to
17 do; you test it. That's the same. It doesn't
18 matter what the intervention is.

19 The -- the process of making
20 inference is the same when you are comparing --
21 in -- in a parallel group randomized trial,
22 which is what we are talking about, it's --
23 it's the nature of the design, not the nature
24 of the intervention, that defines how you
25 design it and how you analyze the data.

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2 Q. So in your opinion, are you saying
3 that the process for a drug manufacturer to get
4 a drug approved should be the same as the
5 process for a dietary supplement manufacturer
6 to --

7 MS. SOBERATS: Objection.

8 BY MR. GRAHAM:

9 Q. -- sell a dietary supplement.

10 MS. SOBERATS: Objection.

11 Mischaracterizes the witness's testimony and
12 this is outside the scope of her expertise and
13 reports.

14 THE WITNESS: Yeah. I have not
15 opined at all about the standards for
16 approve -- for drug or supplement approval.
17 That's a whole different -- what a manufacturer
18 does, that is a whole different field that's
19 outside my field of expertise.

20 BY MR. GRAHAM:

21 Q. Okay. And your -- your opinions on
22 this -- on the standard, as we called it, for
23 RCTs, what are you basing your opinions on?

24 A. Fifty years of -- of training and
25 experience and teaching and reading and

1 JANET WITTES, PH.D.

2 designing studies and giving talks, writing
3 papers, writing books.

4 Q. Anything else?

5 A. I think that covers it.

6 Q. Are you basing your opinion on any
7 law or regulation?

8 A. I am not basing my opinion on laws
9 or regulations.

10 Q. In Paragraph 78 of your report, you
11 conclude that it is your opinion that the
12 Madison Memory Study does not provide evidence
13 of any benefit of Prevagen.

14 Do you see that?

15 MS. SOBERATS: What -- what part of
16 70 -- are you on Paragraph 75, Glen?

17 MR. GRAHAM: 78.

18 THE WITNESS: 78.

19 MS. SOBERATS: 78. What part of
20 Paragraph 78 are you referring to again?

21 MR. GRAHAM: It is the last sentence
22 of Paragraph 78, last three lines. Begins
23 after report. It is my opinion that the
24 Madison Memory Study does not provide evidence
25 of any benefit of Prevagen.

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2 Q. Didn't the inclusion criteria of the
3 Madison Memory Study protocol focus on those
4 individuals who would have scoring between zero
5 to two on the AD8 screening test?

6 A. No, it did not. The -- the protocol
7 did not focus on those.

8 Q. And what is your -- the basis for
9 your opinion on that?

10 A. Entry criteria number one.

11 Q. You mean the Inclusion Criteria?

12 A. Yes, Inclusion Criteria Number One.
13 It has nothing to -- it doesn't talk about the
14 degree of mem- -- cognitive or memory decline.
15 It just says that the subject has ongoing
16 difficulties, doesn't say how much, and ongoing
17 concern.

18 Q. You're referring to number one in
19 the inclu- -- Inclusion Criteria: "Subject has
20 ongoing memory difficulties and concern about
21 the current status of their memory/decline or
22 cognitive abilities associated with the aging
23 process"? Is that what you're referring to?

24 A. That's what I'm referring to.

25 And it's actually -- it's really

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2 hard to read because the "or" isn't clear,
3 right? Concern about -- you can read it in one
4 of two ways. Concerned about the current
5 status of their memory decline, A; or B,
6 cognitive abilities associated with the aging
7 process.

8 The other way you could read it is
9 "and concerned about the current status of the
10 memory/decline cognitive abilities) associated
11 with the aging process."

12 So this is a very ambiguous -- and
13 is another problem. There is -- there's an
14 "and" and an "or." It's very ambiguous, but it
15 seems to be anybody who has ongoing memory
16 difficulties and concern, and then I don't
17 really know how the "or" fits in.

18 Q. So your opinion that the protocol in
19 the Madison Memory Study did not focus on the
20 AD8 zero to two subgroups is because of this
21 sentence in Paragraph 1 of Inclusion Criteria?

22 MS. SOBERATS: Objection to the
23 form.

24 THE WITNESS: This sentence doesn't
25 specify zero to two, nor does anything else in

1 JANET WITTES, PH.D.

2 the protocol.

3 BY MR. GRAHAM:

4 Q. So is it your opinion because the
5 letters AD8, zero to two, are not in the
6 protocol that is not prespecified analysis?

7 MS. SOBERATS: Objection.

8 Mischaracterizes the witness's testimony.

9 THE WITNESS: There is nothing in
10 the protocol that specifies that the degree of
11 impairment has to be mild or moderate or
12 anything that would correspond to a zero, one,
13 or two. There's nothing in the protocol.

14 I mean, can we keep on going down?
15 Let's look at the rest of the protocol. Let's
16 look at the Exclusion Criteria.

17 BY MR. GRAHAM:

18 Q. Sure. So in the --

19 A. Oh, I can't do this. Sorry. Sorry.
20 I have to -- yes. So --

21 Q. In the exclusion -- Dr. Wittes, in
22 the Exclusion Criteria, the Madison Memory --
23 excuse me, the Madison Memory Study protocol in
24 the Exclusion Criteria section includes those
25 with a significant neurological disease or

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CERTIFICATE OF NOTARY PUBLIC

I, Bonnie L. Russo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to computerized transcription under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

Dated: October 15th, 2021

Bonnie L. Russo

Bonnie L. Russo
Notary Public in and for
the District of Columbia

My Commission expires: August 14, 2025

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

Case No. 1:17-cv-00124-LLS

FEDERAL TRADE COMMISSION and
THE PEOPLE OF THE STATE OF NEW
YORK, by LETITIA JAMES, Attorney
General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited
liability company;

PREVAGEN, INC., a corporation
d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE
MANUFACTURING, LLC, a limited
liability company; and

MARK UNDERWOOD, individually and as
an officer of QUINCY BIOSCIENCE
HOLDING COMPANY, INC., QUINCY
BIOSCIENCE, LLC, and PREVAGEN,
INC.,

Defendants.

I, Janet Wittes, hereby make the following corrections to the transcript of my deposition,
which occurred on October 7, 2021:

PAGE	LINE(S)	CORRECTION	REASON
13	3	“encompass” should be “encompasses”	Typographical error
16	11	“study that is” should be “study; that is,”	Punctuation error
26	16	“standard” should be “standards”	Typographical error

46	22	“structured or” should be “structure”	Typographical error
51	18	“is” should be “are”	Typographical error
59	18	“design analysis” should be “design and analysis”	Typographical error
60	6	“president emeritus” should be “President Emerita”	Typographical error
61	25	“shared” should be “chaired”	Typographical error
62	9, 10	“women’s health initiative” should be “Women’s Health Initiative”	Typographical error
65	20	“Hotline” should be “Heart, Lung,”	Typographical error
65	24	“ARID” should be “AREDS”	Typographical error
66	17	“INCAM” should be “NCAM”	Typographical error
66	23	“MIDDK” should be “NIDDK”	Typographical error
67	12-14	Should read “All of these were NIH funded”	Typographical error
75	3 and 4	“NIHOBI” should be “NHLBI”	Typographical error
75	8	“NIHOBI” should be “NHLBI”	Typographical error
75	13	“stat collab” should be “Stat Collab”	Typographical error
75	18	“it” should be “it’s”	Typographical error
79	10	“ti” should be “it”	Typographical error
96	14	“collected” should be “conducted”	Typographical error
99	18	“painted” should be “tainted”	Typographical error
107	18	“there for” should be “therefore”	Typographical error

107	24	“mention” should be “mentions”	Typographical error
113	2	“as” should be “of”	Typographical error
119	7	“chose” should be “choose”	Typographical error
127	25	“pseudo ram” should be “pseudo random”	Typographical error
134	20	“they were” should be “there were”	Typographical error
135	24	“preserved” should be “is preserved”	Typographical error
136	5	“sentence” should be “sense”	Typographical error
138	21	“are” should be “is”	Typographical error
140	19	“can” should be “can’t”	Typographical error

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on November 9, 2021.

JANET WITTES